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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/615,158 | 07/07/2003 | Jeffrey P. Gilbard | AVR-005 | 8240 |
| 959 | 7590 | 05/22/2007 | | |
| LAHIVE & COCKFIELD, LLP | | | EXAMINER | |
| ONE POST OFFICE SQUARE | | | FAY, ZOHREH A | |
| BOSTON, MA 02109-2127 | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/22/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/615,158 | GILBARD, JEFFREY P. |
| | Examiner | Art Unit |
| | Zohreh A. Fay | 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

Claims 1-42 are presented for examination.

The amendments and remarks filed on December 26, 2007 have been received and entered.

Claims 1-42 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ueno (U.S. Patent 6,566,398) and Yano et al. (Submitted by the applicant) and further over Troyer et al. (U.S. Patent 6,506,412) and Schneider et al. (U.S. Patent 6,353,022) for the reasons set forth on pages 2-4 of the office action of July 26, 2006 and the following reasons.

Troyer et al. teach the use of omega 3-fatty acids and omega 6-fatty acids in a pharmaceutical formulation for the treatment of dry eye syndrome. See the abstract and claims 1 and 17. Schneider et al. teach the use of Vitamin E as an antioxidant in combination with prostaglandins in an ophthalmic formulation for the treatment of dry eye.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks argues that Ueno does not teach fatty acids, but it teaches fatty acid derivatives for the treatment of dry eye. Applicant's attention is directed to Troyer et al. reference, which teaches the use of fatty acids for the treatment of dry eye. Applicant's arguments regarding the Yano have been noted. Applicant in his remarks argues that Yano does not teach the combination of oil rich in EPA and DHA and vitamin E. Applicant is reminded that the rejection is an obviousness rejection and not anticipation. Furthermore, Schneider et al. teach that addition of

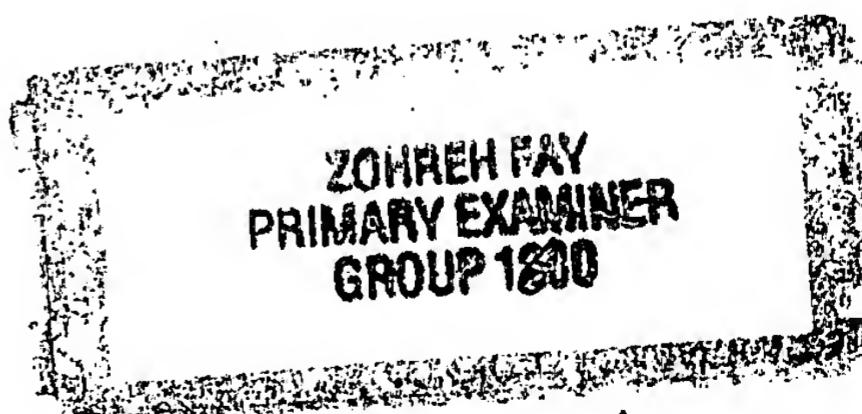
Vitamin E, as an antioxidant to compositions used for the treatment of dry eye as old and well known.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z.F



Zohreh Fay